



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

DEC 19 1994

Re: ALBUNEX®
Docket No. 94E-0360

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

#12

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,844,882 filed by Molecular Biosystems, Inc., under 35 U.S.C. § 156. The medical device claimed by the patent is ALBUNEX®, Premarket Approval Application (PMA) number P900059.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act.

The PMA was approved on August 5, 1994, which makes the submission of the patent term extension application on September 21, 1994, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Freddie K. Park
Morrison & Foerster
755 Page Mill Road
Palo Alto, CA 94304